

Appendix A

Claim Amendments

1. (Currently amended) A pharmaceutical product ~~for preventing or reducing the onset of symptoms of a respiratory disease, or treating or reducing the severity of a respiratory disease,~~ comprising as a free combination
  - (a) an effective amount of roflumilast in a formulation suited for oral or intravenous administration and
  - (b) an effective amount of an anticholinergic agent selected from the group consisting of ipratropium, oxitropium and tiotropium salts in a formulation suited for administration by inhalation.
2. (Currently amended) [[A]] The pharmaceutical product according to claim 1 ~~for preventing or reducing the onset of symptoms of a respiratory disease, or treating or reducing the severity of a respiratory disease,~~ comprising as a free combination
  - (a) an effective amount of roflumilast in a formulation suited for oral administration and
  - (b) an effective amount of an anticholinergic agent selected from the group consisting of ipratropium, oxitropium and

tiotropium salts in a formulation suited for administration by inhalation.

3. (Currently amended) [[A]] The pharmaceutical product according to claim 1 ~~for preventing or reducing the onset of symptoms of a respiratory disease, or treating or reducing the severity of a respiratory disease,~~ comprising as a free combination

- (a) an effective amount of roflumilast in a formulation suited for intravenous administration and
- (b) an effective amount of an anticholinergic agent selected from the group consisting of ipratropium, oxitropium and tiotropium salts in a formulation suited for administration by inhalation.

4. (Currently amended) [[A]] The pharmaceutical product according to claim 1, 2~~or~~3 wherein the anticholinergic agent is tiotropium bromide or tiotropium bromide monohydrate.

5. (Currently amended) [[A]] The pharmaceutical product according to claim 1, 2~~or~~3 wherein the anticholinergic agent is ipratropium bromide.

6. (Currently amended) [[A]] The pharmaceutical product according to claim 1, ~~2 or 3~~ wherein the anticholinergic agent is oxitropium bromide.

7. (Currently amended) [[A]] The pharmaceutical product according to claim 1 ~~any one of claims 1 to 6~~, wherein roflumilast represents 3-cyclopropylmethoxy-4-difluoromethoxy-N-(3,5-dichloropyrid-4-yl)benzamide.

8. (Currently amended) [[A]] The pharmaceutical product according to claim 1 ~~any one of claims 1 to 6~~, wherein roflumilast represents 3-cyclopropylmethoxy-4-difluoromethoxy-N-(3,5-dichloro-1-oxypyrid-4-yl)benzamide.

9. (Currently amended) A method for preventing or reducing the onset of symptoms of a respiratory disease, or treating or reducing the severity of a respiratory disease by administering simultaneously or sequentially, close in time or remote in time, in any order whatever to a patient in need thereof (1) an effective amount of roflumilast orally or intravenously and (2) an effective amount of an

anticholinergic agent selected from the group consisting of ipratropium, oxitropium and tiotropium salts by inhalation.

10. (Currently amended) [[A]] The method according to claim 9 for preventing or reducing the onset of symptoms of a respiratory disease, or treating or reducing the severity of a respiratory disease comprising [[by]] administering simultaneously or sequentially, close in time or remote in time, in any order whatever to a patient in need thereof (1) an effective amount of roflumilast orally and (2) an effective amount of an anticholinergic agent selected from the group consisting of ipratropium, oxitropium and tiotropium salts by inhalation.

11. (Currently amended) [[A]] The method according to claim 9 for preventing or reducing the onset of symptoms of a respiratory disease, or treating or reducing the severity of a respiratory disease comprising [[by]] administering simultaneously or sequentially, close in time or remote in time, in any order whatever to a patient in need thereof (1) an effective amount of roflumilast intravenously and (2) an effective amount of an anticholinergic agent

selected from the group consisting of ipratropium, oxitropium and tiotropium salts by inhalation.

12. (Currently amended) [[A]] The method according to claim 9, ~~10 or 11~~, wherein the two active compounds are administered sequentially, close in time or remote in time, in any order whatever.

13. (Currently amended) [[A]] The method according to claim 9, ~~10, 11 or 12~~ wherein the anticholinergic agent is tiotropium bromide or tiotropium bromide monohydrate.

14. (Currently amended) [[A]] The method according to claim 9, ~~10, 11 or 12~~ wherein the anticholinergic agent is ipratropium bromide.

15. (Currently amended) [[A]] The method according to claim 9, ~~10, 11 or 12~~ wherein the anticholinergic agent is oxitropium bromide.

16. (Currently amended) [[A]] The method according to claim 9 ~~any one of claims 9 to 15~~, wherein roflumilast represents

3-cyclopropylmethoxy-4-difluoromethoxy-N-(3,5-dichloropyrid-4-yl)benzamide.

17. (Currently amended) [[A]] The method according to claim 9 any one of claims 9 to 15, wherein roflumilast represents 3-cyclopropylmethoxy-4-difluoromethoxy-N-(3,5-dichloro-1-oxypyrid-4-yl)benzamide.

18. (Currently amended) [[A]] The method according to claim 9 any one of claims 9 to 17, wherein the respiratory disease is COPD.

19. (Currently amended) Medicament A medicament pack, containing (a) roflumilast as active ingredient in a formulation suited for oral or intravenous administration and (b) a description that roflumilast can be administered, for reducing the onset of symptoms of a respiratory disease, or for treating or reducing the severity of a respiratory disease together with an anticholinergic agent selected from the group consisting of ipratropium, oxitropium and tiotropium salts in a formulation suited for administration by inhalation, sequentially, where the

sequential administration is close in time or remote in time  
and in any order whatever.